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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,237	09/08/2003	Bradley Smith	UNND-0031-4	1095
22506	7590	05/09/2006	EXAMINER	
JAGTIANI + GUTTAG 10363-A DEMOCRACY LANE FAIRFAX, VA 22030			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/656,237

Applicant(s)

SMITH, BRADLEY

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 6-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/8/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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**1)** Applicant's election of Group I, claims 1-5 in the reply filed on February 28, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

**2)** Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**3)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**4)** Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** For claim 5, it is unclear what is meant by the term "said compound is calcium independent". This descriptive term may be a recitation of an inherent feature of the compound(?) but does not, however, further limit the method of claim 5 relative to the method of claim 1.

**b)** The detection step as recited in claim 1 is indefinite and confusing. The claim language appears to indicate that the PSS-380 structure emits fluorescence only upon "association of said compound with said anionic phospholipids". This appears to be inconsistent with the Ojida et al reference {JACS 2002, 124, 6256-6258}, cited by applicant, that indicates that this compound *per se* is fluorescent and that a change in fluorescence emission spectrum response is to be expected upon association of the compound with a phosphorylated peptide. It is also unclear what is meant by the claim term "fluorescence emission". Fig. 1 of this application describes a "fluorescence emission" determination while Fig. 2 describes a "fluorescence

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intensity" measurement. A "fluorescence intensity" measurement would not appear to be included by the term "fluorescence emission". Clarification is required.

c) To conform to standard claim practice, claim 1 must be amended to end in a period (.) and to include the chemical structure before said period (.).

5) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6) Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reutelingsperger (US 5,834,196) taken in combination with Ojida et al (*JACS* 2002, 124, 6256-6258).

Reutelingsperger describes a method of determining phosphatidylserine (an anionic phospholipid) associated with a sample of cells using a fluorescence-based detection agent which has a high affinity for phosphatidyl serine (see col. 6, lines 48-53; claims 1, 18 and 20). The Reutelingsperger method does not use the particular dipicolylamine zinc (II) compound depicted in claim 1 of this application.

Ojida et al describe the dipicolylamine zinc (II) compound depicted in claim 1 of this application as being a fluorescent sensor which binds "phosphorylated chemical species" including phosphorylated amino acids (e.g. p-Tyr) and peptides (*Chart 2.*). See compound 1; the first column of page 6256; *Figures 1 – 3.*

Given the fact that both the Reutelingsperger and Ojida et al methods are directed to the fluorescence-based detection of phosphorylated amino acids/peptides, it would be obvious to substitute the dipicolylamine zinc (II) compound of Ojida et al (known to bind phosphorylated amino acids) as an equivalent phosphorylated amino acid-binding fluorescent label in the method of Reutelingsperger, as

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claimed, with the expectation of obtaining a similarly useful method for the fluorescence-based detection of phosphatidyl serine (a phosphorylated amino acid).

The variation in the "calcium environment" of the dependent claims constitutes an obvious variation in a parameter which is routinely modified in the art of cell detection (see Reutelingsperger, col. 7, lines 39-42; col. 5, lines 19-21) and which has not been described as critical to the practice of the invention.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 28, 2006



Mary (Molly) E. Ceperley  
Primary Examiner  
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